# In the United States Court of Federal Claims Office of special masters No. 21-1720V

YVETTE MOYLER,

Chief Special Master Corcoran

Petitioner,

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Filed: March 12, 2025

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Thomas Joseph O'Connell, Abramson & O'Connell, LLC, Columbus, OH, for Petitioner.

Alexa Roggenkamp, U.S. Department of Justice, Washington, DC, for Respondent.

## **DISMISSAL DECISION**<sup>1</sup>

On August 18, 2021, Yvette Moyler filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*<sup>2</sup> (the "Vaccine Act"). Petitioner alleges that as a result of a tetanus-diphtheria-acellular pertussis ("Tdap") vaccine received on September 9, 2019, she suffered from brachial neuritis ("BN") as defined on the Vaccine Injury Table (the "Table"). Pet., ECF No. 1. The case was assigned to the Special Processing Unit ("SPU") of the Office of Special Masters.

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<sup>&</sup>lt;sup>1</sup> Because this Decision contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the Decision will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

<sup>&</sup>lt;sup>2</sup> National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

For the foregoing reasons, I find that Petitioner has provided insufficient proof of severity of injury, as required for all Vaccine Act claims. See Section 11(c)(1)(D)(i).<sup>3</sup> Petitioner's claim is thus **DISMISSED**.

## I. Relevant Procedural History

Along with the filing of her petition, medical records, and affidavits, Petitioner filed a preliminary expert report plus medical literature exhibits. See ECF No. 1; see also ECF Nos. 20-27.<sup>4</sup> At a May 2022 initial status conference, I noted that (among other things) there was a potential issue regarding Petitioner's ability to satisfy the six-month severity requirement – and ordered Petitioner to file additional medical records and/or affidavits to overcome this issue. ECF No. 20 at 2. In response, Petitioner submitted three additional affidavits – two authored by friends of Petitioner's and the third authored by Petitioner herself. ECF No. 25. The parties thereafter made an effort to informally resolve this case but were ultimately unsuccessful. See ECF Nos. 31-37.

Respondent filed his Rule 4(c) Report defending this case in June 2023. ECF No. 39. Among other things,<sup>5</sup> Respondent contended that Petitioner had not established the existence of residual effects of the alleged injury for more than six months after the September 9, 2019 vaccination. Respondent's Report at 8 (citing Section 11(c)(1)(D)(i)). This is due to the existence of a substantial temporal gap in the medical records during which Petitioner did not report ongoing symptoms. *Id.* at 8-9. Respondent argued the record actually suggests that Petitioner's symptoms resolved a few weeks post vaccination – supported by the fact that she had four intervening medical visits without reporting continued shoulder/arm pain during the gap in care. *Id.* at 9. More so, during the gap in care Petitioner started a new job requiring additional lifting and carrying, which she believed exacerbated her pain, leading her to seek further care. *Id.* Finally, Respondent contended that Petitioner's reported symptoms were different immediately post vaccination than they were following the nine-month gap. *Id.* 

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<sup>&</sup>lt;sup>3</sup> Petitioner does not allege, nor would the evidence support, either alternative for establishing the severity requirement: that the alleged injury resulted in death, or "inpatient hospitalization and surgical intervention." Section 11(c)(1)(D)(ii), (iii). Rather, this case turns on Petitioner's inability to prove six months of post-onset sequelae.

<sup>&</sup>lt;sup>4</sup> Due to several filing errors (Exs. 1-18, ECF Nos. 1, 8, 12) the exhibits were stricken from the record and re-filed in June 2022. See ECF Nos. 20-27.

<sup>&</sup>lt;sup>5</sup> Respondent also argued Petitioner cannot establish a Table BN claim as none of her treating physicians diagnosed her with BN and because she has multiple other conditions or abnormalities present that could explain her post-vaccination symptoms (i.e., carpal tunnel syndrome, *uncontrolled* insulin-dependent diabetes mellitus, and breast cancer). Respondent's Report at 11-12 (emphasis added).

After a review of the record and Respondent's arguments, I issued an Order to Show Cause, again affording Petitioner an opportunity to submit any additional evidence to remedy the deficiencies in the record related to the statutory six-month severity requirement. ECF No. 40. But I warned Petitioner that my ultimate severity analysis would start with the medical record documentation, albeit supplemented by declarations or affidavits. *Id.* at 4.

In response, Petitioner submitted medical records (outside the pertinent gap in treatment bearing on severity) and supplemental affidavits. ECF Nos. 41-43. She also filed a supplemental expert report and medical literature, along with *another* expert report from a spine and sport medicine specialist. ECF No. 42. Having reviewed Petitioner's additional evidence, Respondent filed a status report stating his intention to continue defending this matter and requesting to file his own expert reports. ECF No. 44. The issue of severity is now ripe for adjudication.

## II. Contemporaneous Medical Records

Petitioner's pre-vaccination medical history is relevant for type II diabetes mellitus, hypertension, and carpal tunnel syndrome ("CTS") in her left wrist. See generally Exs. 2-3; Ex. 15.

Petitioner received the subject Tdap vaccination in her left deltoid on September 9, 2019. Ex. 2 at 113. She then sought care for shoulder-related complaints on September 21, 2019 (at an urgent care facility), and again two days later, on September 23, 2019 (with the internal medicine specialist/primary care physician ("PCP") who administered the subject vaccination). Ex. 4 at 3-4; Ex. 2 at 117. During Petitioner's September 23<sup>rd</sup> appointment, she reported that she had developed left upper extremity ("UE") pain at the site of her vaccination. Ex. 2 at 117-18. She described the pain as a "toothache." *Id.* at 118. A physical examination showed normal range of motion ("ROM") but tenderness over the left deltoid. *Id.* at 120. The PCP felt that Petitioner suffered a "[I]ikely localized reaction following administration of her Tdap vaccination[,]" and recommended cold compresses and Tylenol. *Id.* at 118, 122.

On September 25, 2019, Petitioner underwent a left shoulder ultrasound, and it yielded normal results (it did not contain evidence of fluid collection or abscess "to account for [Petitioner's] pain and swelling of the left upper arm"). Ex. 2 at 131-32. Five days later, on September 30, 2019, Petitioner called her PCP's office to review the results of her ultrasound. *Id.* at 127. During that call, Petitioner stated that she "continue[d] to have arm pain after injection" and that she could now barely lift her arm. *Id.* The PCP told Petitioner to continue with cold compresses, Tylenol, and to keep her arm mobile. *Id.* Petitioner did not return to care for her left shoulder/arm soon thereafter.

Rather, Petitioner only returned to care for left UE symptoms approximately *nine months* later, on June 14, 2020. Ex. 2 at 138. However, during this gap in treatment she had in-person follow-up visits with her PCP on December 2, 2019 (for diabetes, hypertension, and a headache) and March 2, 2020 (for diabetes). Ex. 18 at 80-90, 93-108. More so, on April 9 and May 21, 2020, Petitioner had telemedicine follow-up visits with her PCP, again for her pre-existing diabetes and hypertension. *Id.* at 63-66, 73-76. Petitioner did not complain of shoulder symptoms at any of these four visits.

Petitioner then went to the emergency room ("ER") on June 14, 2020, reporting left arm and neck swelling present "ever since she got a tetanus shot in September." Ex. 2 at 138. She described "localized swelling to her left shoulder [that would] sometimes go to her upper arm and into her neck." *Id.* Petitioner also noted that she "got a new position at a memory care unit where she [was] doing a lot of lifting [and] carrying [and] she feels the swelling and burning pain [had] gotten worse." *Id.* She reported that the swelling and burning pain "stop[ped] before it g[ot] to the elbow" but was present in the trapezius and neck. *Id.* A physical examination was consistent with mild swelling in the left deltoid/outer arm and tenderness in the trapezius muscle. *Id.* at 141. An x-ray of the left shoulder was "unremarkable." *Id.* The treater felt that Petitioner had a "blood clot" which "might be from overuse," and he advised her to wear a sling and to take anti-inflammatories and/or muscle relaxers. *Id.* 

The next day (June 15, 2020), petitioner called her PCP's office, informing the treater of her ER visit the previous night and stating that her "left arm is swollen and in pain." Ex. 2 at 133. She also reported neck pain "toward the back" and "a tingling sensation on [her] fingers." *Id.* Petitioner stated that the "[s]welling in [her] arm and neck did not happen until after [her] Tetanus shot." *Id.* Petitioner was seen in-person later that day and reiterated her complaints of "chronic left shoulder pain, left fingertip numbness/tingling and left hand swelling since having a tetanus shot in Sep[tember] 2019." *Id.* at 145. She had normal ROM and strength on examination, but tenderness over the left deltoid. *Id.* at 147. The assessment included chronic left shoulder pain with an "[u]nclear etiology, possibly [osteoarthritis ("OA")]" or an inflammatory process. *Id.* at 145. Petitioner was told to continue taking Flexeril and she received a prescription for Naproxen; an MRI was also ordered. *Id.* 

Petitioner followed up with her PCP on June 22, 2020, complaining of chronic left shoulder pain "present since 9/2019, which she attribute[d] to an immunization she received in the left deltoid." Ex. 2 at 155. She stated her pain was "[w]orse since starting new job." *Id.* She described the pain as "burning" and "primarily over the left shoulder and deltoid area, although sometimes this radiate[d] into the hand." *Id.* Her ROM was also "severely limited due to pain" and she experienced "intermittent swelling." *Id.* The

assessment included "[c]hronic pain/swelling after an immunization in 9/2019. Worsening x2 months since starting new job. Etiology unclear but seems neuropathic, possibly referred pain from CTS. Possible tendonitis vs. radiculopathy. No clear trauma." *Id.* 

On June 24, 2020, another physician at Petitioner's PCP's office reviewed Petitioner's recent history and treatment plan. Ex. 2 at 150. The physician noted that Petitioner's left shoulder pain "[b]egan after getting injection for Tdap vaccine" and that her shoulder x-ray showed "chronic degen[eration], but no acute process." *Id.* The treater opined that "[g]iven the neuropathy, [it was] concerning that this process [was] actually cervical radiculopathy and not her shoulder." *Id.* Petitioner requested an MRI of her shoulder and the physician "discussed with [her] that [he would] rather image her cervical spine based on her history, but since she want[ed her] shoulder imaged, [the] decision was made to image both" the neck and shoulder. *Id.* 

An August 8, 2020 MRI of the left shoulder revealed "diffuse muscle edema and likely changes related to denervation edema." Ex. 2 at 165. The impression was that this was from an "uncertain etiology." *Id.* The findings were also consistent with severe tendinopathy of the supraspinatus and infraspinatus tendons and moderate tendinopathy of the subscapularis with no focal rotator cuff tear. *Id.* There was suspicion for a grade 1 muscle strain based on patchy muscle edema in the supraspinatus tendon; mild bursitis; and moderate tendinopathy involving the biceps tendon. *Id.* 

Petitioner saw an orthopedic surgeon on September 3, 2020, for a chief complaint of pain in the left shoulder. Ex. 2 at 167. Petitioner reported that her "burning" shoulder pain and swelling began "after an immunization injection in 9/2019[,]" and that it has "not resolved since." *Id.* at 168, 171. She also reported associated numbness, tingling, weakness, and limited function. *Id.* at 168. The orthopedist noted that Petitioner was "an uncontrolled diabetic." *Id.* An examination showed full active and passive ROM and slight swelling and tenderness in the distal upper arm. *Id.* at 171. The orthopedist was "unable to replicate her pain with impingement testing or of the rotator cuff[;] this is not the pain that she feels." *Id.* An EMG was recommended. *Id.* 

During a September 4, 2020 telemedicine follow up with her PCP, Petitioner reported continued "burning" left shoulder pain, swelling in her arm, and hand numbness. Ex. 2 at 175. The PCP reiterated the belief that Petitioner's left shoulder pain had an "[u]nclear etiology but appears neuropathic in nature, after Tdap immunization in 9/2019." *Id.* Petitioner was prescribed gabapentin and referred to a neurologist. *Id.* 

Petitioner underwent an EMG of the left UE<sup>6</sup> on September 23, 2020. Ex. 2 at 180. The EMG was considered "abnormal" with findings "consistent with a moderately severe, left median entrapment neuropathy across the carpal tunnel without significant axonal involvement." Id. Petitioner's PCP reviewed the findings with her and explained they were "consistent with [CTS], but did not reveal any other findings that would explain her symptoms in the shoulder region." Id. at 178. The PCP told Petitioner that a cervical MRI should still be completed "as there may be a radicular component of pain." Id. Petitioner expressed "deep frustration" and that she was "being ignored." Id. Specifically, Petitioner explained that

[t]he vaccination [] started this entire cascade of pain and testing was in the lower arm near the elbow, and that she had an obvious bulge, which ha[d] been present since the vaccination . . . . She [] has pain only at the area of the bulge, and not at the shoulder at this time, and this is where the pain has always been located.

Id. The PCP noted that Petitioner "was told that on evaluation of her prior clinic notes, there was no note of a bulge." Id. Petitioner was instructed to obtain an in-person evaluation of this bulge. *Id.* Petitioner did not attend an in-person evaluation.

During a November 24, 2020 telemedicine visit with her PCP, Petitioner, among other things, complained of a "bulge in her forearm that [wa]s in pain." Ex. 18 at 27. She described shooting pain in her shoulder and down to her hand, plus hand swelling. Id. The PCP felt that Petitioner should "[c]onsider small fiber neuropathy" as a potential diagnosis and stated she may need a skin biopsy to confirm as much. Id.

Petitioner began physical therapy ("PT") for her left shoulder pain on December 7, 2020. Ex. 31 at 8. She described her history stating she received the Tdap vaccine in September 2019 and went to the ER two days later with pain and swelling plus "burning nagging toothache pain" with shakiness and numbness in the arm and hand. Id. at 10. She also described neck pain, beginning "around the same time as the injection that still remains." Id. The physical therapist noted that Petitioner's symptoms were "consistent with left UE radiculopathy possibly in C6-C7 dermatome pattern from left 1st rib depression, poor posture[,] and brachial plexus tension." Id. at 8. She attended seven additional PT appointments before discontinuing PT on January 19, 2021. See id. at 13-45.

<sup>&</sup>lt;sup>6</sup> This EMG does not appear to have tested the infraspinatus or supraspinatus tendons of the left subscapular nerve. Ex. 2 at 181.

On January 8, 2021, Petitioner followed up with her PCP, who still felt that her shoulder pain had an unclear etiology "though [it] appear[ed] neuropathic in nature." Ex. 18 at 6. A May 6, 2021<sup>7</sup> repeat EMG of the left UE showed severe isolated involvement of the left suprascapular nerve and moderate left CTS. Ex. 6 at 2. It did not show any evidence of cervical radiculopathy, brachial plexopathy, myopathy, or polyneuropathy. See *id*.

#### III. Affidavits

Through affidavits (some specifically drafted after my Order to Show Cause highlighting the specific deficiencies in the record related to severity), Petitioner maintains that she can establish the Act's six-month requirement. She attests that during her September 23 and 30, 2019 visits, her PCP "did not instruct [her] to return for further evaluation or treatment." Ex. 22 ¶¶ 7-8. As a result, between September 30, 2019, and June 14, 2020, she "did not seek any further medical evaluation of [her] left arm pain" - despite persistent pain - because "it was [her] impression from the communications with the office of [her PCP] that there was no other treatment that could be provided for [her] complaints." *Id.* ¶¶ 9-10. Petitioner explains that she "hoped that the pain would go away but it did not." *Id.* ¶ 9. Following her September 30, 2019 visit, she contends that the "most severe" pain that made it "unbearable to lift [her] arm continued for about one month." Ex. 33 ¶ 10. She then had ongoing difficulties with reaching for a shelf or behind her back, lifting heavy items, or sleeping. *Id.* 

Petitioner addresses her position at an assisted living facility and explains that she began this position "[o]n or about May 1, 2020." Ex. 22 ¶ 11. She attests that she already had pain in her left arm and shoulder when she began working at this facility, but she took the job due to employment and financial concerns. Ex. 33 ¶¶ 16, 21. The duties included "assisting residents with transfers in and out of wheelchairs, beds, and showers[,] cleaning, laundry, lifting food trays and trash removal." Ex. 22 ¶ 11. Petitioner states that the lifting made her arm pain worse, which prompted her to go to the ER on June 14, 2020, and seek additional shoulder and neck treatment thereafter. *Id.* ¶¶ 11-12; Ex. 33 ¶ 17. Due to her ongoing pain, Petitioner stopped working at this facility on July 4, 2020. Ex. 22 ¶ 13. She claims that she did not "suffer any new injury to [her] left arm or shoulder during the time she worked at" this facility. Ex. 33 ¶ 21. Rather, "by the summer of 2020" it became clear to Petitioner that her symptoms "that began after [] the vaccine the

<sup>&</sup>lt;sup>7</sup> During the time between Petitioner's last follow-up visit with her PCP for left shoulder symptoms in January 2021 and her May 2021 EMG, Petitioner had been diagnosed with, and began treatment for, breast cancer. See, e.g., Ex. 25 at 17, 333-49; Ex. 26 at 6; Ex. 27 at 16-21, 43-45; Ex. 28 at 28, 124. Such treatment extended through June 2022. See *generally* Exs. 29-30.

<sup>&</sup>lt;sup>8</sup> The contact with Petitioner's treater regarding ongoing shoulder pain on September 30, 2019, appears to have been a phone call, not an in-person visit. Ex. 2 at 127.

previous September were not only continuing but would get much worse" if she continued to use her arm in this employment. *Id.* ¶ 22.

Petitioner also provides more context for some of the entries in her medical records. For instance, Petitioner explains that when she described her pain at her September 23, 2019 visit as a "toothache," she was "trying to describe an intense, burning type of pain" and the "best comparison that came to mind was intense pain [she had] previously experienced during dental procedures." Ex. 33 ¶ 7. Additionally, she states she did not mention left shoulder complaints at her PCP visits during the gap in treatment because these appointments were regular follow ups and at that time, she was "no longer experiencing the worst pain . . . where [she] could barely lift [her] arm." *Id.* ¶¶ 14-15.

Petitioner's friend authored an affidavit on her behalf and attests that Petitioner complained to her of pain in her upper left arm, "includ[ing] the time period of September 30, 2019 to June 14, 2020." Ex. 23 ¶ 7. This friend explains that she would take her mother to Petitioner's house "in the fall of 2019" – during which time Petitioner told the friend of ongoing shoulder pain. Ex. 34 ¶ 3. The friend's mother passed away on April 11, 2020, and "between the time [Petitioner] received her vaccine injection in September 2019 and [her] mother's death on April 11, 2020," Petitioner told her of continued upper left arm pain. *Id.* ¶ 4. Another friend of Petitioner's attests that Petitioner complained to her of ongoing pain following her September 2019 visits and "throughout 2020." Ex. 24 ¶¶ 5-7.

Petitioner's daughter authored an affidavit on her mother's behalf (also in response to my Order to Show Cause) and states that "[d]uring spring break of 2020[,]" on March 16, 2020, she moved home with Petitioner – who "was still having pain in her left arm and shoulder." Ex. 35 ¶¶ 5-6. She also states that Petitioner's pain became "worse because of the type of work she had to do" with her job at the assisted living facility (beginning in May 2020). *Id.* ¶ 8.

### IV. Petitioner's Experts' Arguments

Petitioner was warned on several occasions not to retain a medical expert, life care planner, or other expert without consulting with Respondent and obtaining leave from me, with reimbursement of those costs risked if she acted otherwise. See, e.g., ECF No. 17 (SPU Initial Order, issued on April 15, 2022); ECF No. 20 (Scheduling Order, issued following an initial status conference on May 26, 2022); ECF No. 32 (Scheduling Order, issued on November 4, 2022). Despite such warnings (and failing to consult with Respondent and/or the court), Petitioner has submitted expert reports from two physicians, which consist of the experts' answers to various questions posed by

Petitioner's counsel. I will consider the arguments made by Petitioner's experts to the extent that they relate to the specific issue of severity.

First, Petitioner submitted an expert report from Dr. Scott Lipson (and corresponding medical literature), which was authored in August 2021 following a telemedicine visit with Petitioner. Ex. 7. Dr. Lipson specializes in neurophysiology. *Id.* at 1. He did not address Petitioner's lengthy gap in treatment but contended that Petitioner's left shoulder pain "continued through May 2021," or through the time of her repeat EMG that month. *Id.* at 10. Dr. Lipson argued that Petitioner's clinical presentation and diagnostic findings were consistent with "isolated suprascapular neuropathy as the manifestation of her [BN]" – which caused atrophy of the supraspinatus and infraspinatus nerves and severe denervating changes. *Id.* at 10-11. Dr. Lipson concluded that the "most obvious cause" of Petitioner's shoulder symptoms was "post-vaccine [BN]." *Id.* at 12.

In a supplemental report (drafted in response to my Order to Show Cause), Dr. Lipson homed in on the severity issue at hand. He was not surprised by Petitioner's reported "worsening pain" in June 2020, after using her left arm more at a new job. Ex. 36 at 2. He opined this "exacerbation" was "entirely consistent with her known suprascapular neuropathy" – which is characterized by the most severe pain at the beginning of the disorder, followed by the pain becoming more neuropathic then musculoskeletal. *Id.* at 2-3. To him, this did not suggest "the development of a new cause for shoulder pain" but is instead consistent with her course of BN. *Id.* Additionally, Dr. Lipson asserted that because Petitioner's PCP did not suggest or diagnose "suprascapular mononeuropathy/[BN]" – a diagnosis he claimed is often missed by PCPs – or order any additional diagnostic tests beyond an ultrasound, Petitioner chose not to return to care after September 2019. *Id.* at 3.

Second, Petitioner submitted an expert report from Dr. Joseph Feinberg, a specialist in neuromuscular and electrodiagnostic medicine. Ex. 40 at 1. Dr. Feinberg opined that Petitioner had "chronic and recurrent pain that has persisted for well beyond six months from the time she first reported symptoms on 9/21/19." *Id.* at 2. He further opined that her complaints "in September of 2019, June of 2020, and thereafter were caused by the Tdap vaccine." *Id.* He contended that Petitioner's presentation was classic of BN "secondary to a vaccination and there is no other plausible explanation for her symptoms and diagnostic [] findings." *Id.* Dr. Feinberg argued that Petitioner's first EMG (performed in September 2023) did not test the suprascapular nerve and was thus "inadequate[,]" which is why the correct diagnosis was not made until her repeat EMG in May 2021. *Id.* at 1.

## V. Applicable Legal Standard

Petitioners carry the burden of establishing the matters required in the petition by a preponderance of the evidence. Section 13(a)(1)(A). One such requirement is "documentation demonstrating that [the petitioner]<sup>9</sup> ... suffered the residual effects or complications of such [vaccine-related] illness, disability, injury, or condition for more than 6 months after the administration of the vaccine." Section 11(c)(1)(D)(i); see also Black v. Sec'y of Health & Hum. Servs., 33 Fed. Cl. 546, 550 (1995) (reasoning that the "potential petitioner" must not only make a *prima facie* case, but clear a jurisdictional threshold, by "submitting supporting documentation which reasonably demonstrates that a special master has jurisdiction to hear the merits of the case"), aff'd, 93 F.3d 781 (Fed. Cir. 1996) (internal citations omitted).

Congress has stated that the severity requirement was designed "to limit the availability of the compensation system to those individuals who are seriously injured from taking a vaccine." H.R. REP. 100-391(I), at 699 (1987), reprinted in 1987 U.S.C.C.A.N. 2313–1, 2313–373, cited in *Cloer v. Sec'y of Health & Hum. Servs.*, 654 F.3d 1322, 1335 (Fed. Cir. 2011), *cert. denied*, 132 S.Ct. 1908 (2012); *Wright v. Sec'y of Health & Hum. Servs.*, 22 F.4th 999, 1002 (Fed. Cir. 2022).

The Act prohibits finding a petition requirement "based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." Section 13(a)(1). Medical records must be considered, see Section 13(b)(1), and are generally afforded substantial weight. *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). *Murphy v. Sec'y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 74931, \*4 (Fed. Cl. Spec. Mstr. April 25, 1991), quoted with approval in decision denying review, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed.Cir.1992)). However, the Federal Circuit has recently "reject[ed] as incorrect the presumption that medical records are accurate and complete as to all the patient's physical conditions." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021).

It is thus certainly the case that factual matters required to prove elements of a Vaccine Act claim may be established by a *mix* of witness statements and record proof, with the special master required to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe v. Sec'y of Health & Hum. Servs.*, 110 Fed. Cl. 184 (2013) (citing Section 12(d)(3); Vaccine Rule 8), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

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<sup>&</sup>lt;sup>9</sup> Or other vaccinee, e.g., a minor or other person who is unable to represent his or her own interests, on behalf of whom the claim is brought.

## VI. Analysis

I note preliminarily that Petitioner not only had opportunity to prepare her claim prior to filing, but was repeatedly put on notice over the subsequent duration of the case that severity was an issue to be addressed. Yet even after Respondent submitted his formal position in his Rule 4(c) Report (resulting in an Order to Show Cause), Petitioner has not submitted additional evidence or established why additional time is merited to obtain such evidence. Petitioner has thus now had a "full and fair opportunity" to support her position. Vaccine Rule 3(b). Based upon that existing record (and despite Respondent's request for responsive expert reports), I find dismissal is warranted.

Assuming arguendo<sup>10</sup> that Petitioner's initial post-vaccination complaints and symptoms were, in fact, consistent with BN as alleged, the filed medical records suggests that her injury was initially severe upon onset but improved over time, and thus did not require much formal medical treatment to resolve. Indeed, after her September 25, 2019 ultrasound, which did not find anything to "account for [her] pain and swelling of the left upper arm," she was told to use home treatments, like cold compresses and Tylenol as needed. Ex. 2 at 127, 131-32. There was thus some medical expectation that treatment of the injury might not be needed for a substantial period of time – which would have been only *three weeks* after vaccination.

In addition, the record does not corroborate Petitioner's severity assertions in other regards. She discontinued treatment for her shoulder injury the same month as her subject vaccination, and there is no subsequent medical record proof that the injury demanded any additional medical evaluation for approximately nine months. Indeed, the records do not show a single follow-up visit for evaluation of her shoulder symptoms between September 30, 2019, and June 14, 2020 (in comparison to the records showing ongoing care for pre-existing ailments with the same PCP who administered the subject vaccination, and with whom she previously sought shoulder/arm related treatment prior to the gap in care).

Petitioner, however, maintains that following her September 2019 visits with her PCP, her physician "did not instruct [her] to return for further evaluation or treatment." Ex. 22 ¶¶ 7-8. She thus believed that "there was no other treatment that could be provided for [her] complaints." *Id.* ¶¶ 9-10. She also attests that she did not complain of shoulder-related complaints at intervening PCP visits because these appointments were regular

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<sup>&</sup>lt;sup>10</sup> There appears to also be a dispute among the parties regarding whether Petitioner's initial post-vaccination symptoms and diagnostic findings were consistent with a Table BN injury and/or whether she was, in fact, ever diagnosed with BN by any of her treaters. See Respondent's Report at 11-13; see also Exs. 36, 40. In light of severity being a dispositive issue, however, I do not address diagnosis.

follow ups, and at that time she was "no longer experiencing the worst pain . . . where [she] could barely lift [her] arm." Ex. 33 ¶¶ 10, 14-15. She again was hopeful the pain would subside, and believed "there was no other treatment that could be provided." Id.

While there is some reason to credit such arguments, they are ultimately unpersuasive given the totality of evidence. Petitioner's contention, for example, that medical providers did not propose much in the way of treatment for her shoulder pain after September 2019 does have record support. But at the same time, Petitioner had several in-person and telehealth visits with her PCP (the same person who provided her initial UE treatment – and thus would have been already aware of her vaccine-related complaints) during the subsequent treatment gap. Accordingly, she had ample opportunity to mention such problems, had they continued to linger as alleged, and despite earlier suggestions that only limited, conservative treatment was possible.

Petitioner further points to record evidence establishing that beginning from when she returned to care on June 14, 2020 (nine months after treatment cessation), she consistently associated her ongoing pain to her earlier vaccination. See, e.g., Ex. 2 at 138 (a June 14, 2020 note stating Petitioner presented for arm pain "ever since she got a tetanus shot in September"); Ex. 2 at 145 (a June 15, 2020 follow up for "chronic left shoulder pain since tetanus shot in Sep[.] 2019."); Ex. 2 at 155 (a June 22, 2020 note showing a complaint of "[c]hronic pain/swelling after an immunization in 9/2019."); Ex. 2 at 168 (a September 3, 2020 note stating her pain "began after an immunization injection in 9/2019."); Ex. 18 at 7 (a January 8, 2021 note stating Petitioner "continues to have L shoulder/arm pain. Developed after onset of tdap [sic] vaccination in 9/2019.").

In many cases (especially where the treatment gap was shorter, or featured less intervening opportunities to obtain follow-up care for a purported vaccine injury), the foregoing might be sufficient to satisfy severity. But here, there is a competing factor established by the record. For in May 2020, Petitioner began a job at an assisted living facility requiring substantial lifting and carrying elderly patients to and from beds, wheelchairs, and showers. Not only does this suggest that her vaccine-related symptoms (to the extent they existed at the time) were mild enough to take on this kind of work (even with financial concerns), but Petitioner also expressly admitted to medical providers that this job exacerbated her shoulder symptoms. See, e.g., Ex. 2 at 138 (a June 14, 2020 ER report that her new job made her pain worse); Ex. 2 at 155 (a June 22, 2020 report of "[w]orsening [pain and swelling] x2 months since starting new job."); Ex. 22 ¶¶ 11-12 (her first affidavit stating that the lifting required from her new job made her arm pain worse, which prompted her to go to the ER on June 14, 2020, and seek additional shoulder and neck treatment). While an argument could be made that the physical labor associated

with the new job merely exacerbated the prior vaccine injury, this record leans more in favor of the conclusion that the new position caused an entirely different injury.

In fact, the medical records show that Petitioner's complaints and physical examination findings *differed* pre and post gap in treatment. Thus, in September 2019 Petitioner complained of left UE pain, and her September 23, 2019 examination showed tenderness at her myofascial trigger point but no edema; diminished ROM was likewise not observed. Ex. 2 at 120. But when Petitioner returned to care in June 2020 following the gap in treatment and thereafter, she consistently reported a different constellation of symptoms - pain into the neck, swelling in the upper left limb (and left hand), numbness/tingling that radiated into her left hand/fingers, and exhibited limited ROM. See, e.g., Ex. 2 at 138, 145, 155, 168; Ex. 18 at 7, 26-27. She also began complaining of weakness in the left arm and a bulge in her forearm. Ex. 18 at 7, 27. While Petitioner's pre-gap medical records are indeed limited, it is apparent that she experienced differing symptoms (in terms of type and location) in September 2019 than in June 2020 and beyond, and thereby further casting doubt on her contentions that the vaccine-related complaints were related to or consistent with her June 2020 concerns.

Even more persuasive on this point is the fact that Petitioner's treaters suspected different etiologies of her symptoms immediately post-vaccination than they did for the symptoms she displayed after the nine-month treatment gap. At Petitioner's September 23, 2019 visit, for instance, her PCP assessed her with a "[I]ikely localized reaction following administration of her Tdap vaccination in her left upper extremity." Ex. 2 at 117-18. By contrast, when Petitioner visited the ER in June 2020 after the gap in care, the ER physician speculated that Petitioner's symptoms were caused by a blood clot formed from overuse with her new job. Id. at 141. And when Petitioner followed up with her PCP on June 15, 2020 (the same treater who knew Petitioner's recent history and previously assessed a localized vaccine reaction), that PCP opined that the cause of her ongoing symptomology had an "[u]nclear etiology" and was "possibly OA" or an inflammatory process. Id. at 145. Later that month, on June 22, 2020, her PCP posited a neuropathic etiology, possibly referred pain from CTS, or tendonitis versus radiculopathy as possible explanations for her pain. Id. at 155. As a result, the PCP urged Petitioner to undergo MRIs of the neck and shoulder, but Petitioner insisted her symptoms were rooted in her shoulder. Id. at 150. Such evidence supports the conclusion that Petitioner was experiencing a manifestation of distinguishable symptoms and/or conditions following the conclusion of her initial vaccine-related care.

I also do not find that the witness statements supplied by Petitioner can overcome the existing medical record discussed above, even if they merit *some* weight. Thus, a third party affidavit obtained from one of Petitioner's acquaintances attests to encounters with Petitioner when she would mention ongoing shoulder pain during the pertinent gap in care, and even provides a rationale for the recollection (that the timeframe sticks in the individual's head due to a personal family loss at the time). See generally Ex. 34. Yet this affidavit (and most of the other supplemental and/or fact affidavits), was authored for the purposes of litigation, after the filing of the instant claim, and even after the issuance of my Order to Show Cause. And it cannot fully rebut the absence of evidence of UE complaints in the timeframe, despite many opportunities to raise the issue with treaters.

The same can be said of Petitioner's expert reports. The timing of these reports provides some grounds for giving them slightly less weight; two of the three expert reports were submitted over two years after the initiation of the instant claim, and following the issuance of my Order to Show Cause. Far more importantly, however, *none* of Petitioner's expert reports specifically address what occurred during the relevant gap in care - and with that, what if any of Petitioner's vaccine-related symptoms were ongoing between September 2019 and June 2020. This was something that an expert could well have provided useful commentary upon, especially since the record clearly establishes that Petitioner *could* have raised UE concerns during the treatment gap. Given Petitioner's limited post-vaccination care prior to the gap, some contextual medical explanation was needed, but these reports did not provide it. I therefore do not give the reports significant weight in resolving severity.

#### CONCLUSION

Petitioner has presented insufficient proof to establish the six-month severity requirement. Section 11(c)(1)(D). Therefore, she is ineligible to pursue compensation under the Program. In the absence of a timely-filed motion for review (see Appendix B to the Rules of the Court), the Clerk of Court shall enter judgment in accordance with this Decision.<sup>11</sup>

IT IS SO ORDERED.

s/Brian H. Corcoran Brian H. Corcoran Chief Special Master

<sup>11</sup> Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment by filing a joint notice renouncing their right to seek review.